No. 84-267

In the Supreme Court of the United States

October Term, 1984

WILLIAM P. CLARK, ET AL.,
Petitioners,

vs.

SOUTHERN OREGON CITIZENS AGAINST TOXIC SPRAYS, INC.,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF AMICUS CURIAE MONSANTO COMPANY IN SUPPORT OF THE PETITION OF WILLIAM P. CLARK, ET AL., FOR A WRIT OF CERTIORARI

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Regulations

Miscellaneous

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OPINIONS BELOW

The opinion of the Court of Appeals, *Southern Oregon Citizens Against Toxic Sprays, Inc. v. Clark,* is reported at 720 F.2d 1475. The opinion of the district court, *Southern Oregon Citizens Against Toxic Sprays v. Watt,* is unreported. (See Petitioners' Appendix, 13a-24a).

JURISDICTION

The judgment of the Court of Appeals was entered on December 2, 1983. A petition for rehearing was denied on March 21, 1984. On June 8, 1984, Justice Rehnquist extended the time for filing a petition for writ of certiorari to and including August 1, 1984. On July 24, 1984, Justice

Rehnquist further extended the time for filing a petition for writ of certiorari to and including August 18, 1984. On or before August 18, 1984 petitioners William P. Clark, et al., filed their petition for writ of certiorari to the United States Court of Appeals for the Ninth Circuit. Respondent sought and was granted an extension of time to and including October 22, 1984 for filing its opposition. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1). Letters from counsel for petitioners and respondent granting consent to the filing of this Brief have been filed with the Clerk of the Court.

STATUTES INVOLVED

Section 102 of the National Environmental Policy Act of 1969, ("NEPA") 42 U.S.C. (& Supp. V) 4321, and relevant provisions of the Federal Insecticide, Fungicide and Rodenticide Act, ("FIFRA") 7 U.S.C. 136 et seq., are reprinted at 27a-33a of Petitioners' Appendix.

INTEREST OF AMICUS CURIAE

Monsanto Company is a developer, manufacturer, and marketer of pesticides[1] including Roundup,* one of the herbicides the Bureau of Land Management ("BLM") proposed to utilize for its vegetation control spraying program. The decision of the Court of Appeals prevented BLM from purchasing and using Monsanto's product pending preparation of the court-ordered NEPA review. No pesticide may be marketed unless it has been registered by the Environmental Protection Agency ("EPA") after extensive testing pursuant to FIFRA. Although Congress has charged EPA with the duty of providing pesticides will

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1. As used in FIFRA and in this Brief, the term "pesticides" includes herbicides as well as a variety of other products such as insecticides and fungicides.

*A registered trademark of Monsanto Company.

not cause unreasonable adverse effects on the environment, the Court of Appeals ruled BLM and any other federal agency using pesticides cannot rely on EPA but must instead independently conduct a scientific analysis of each pesticide the agency proposes to use. This court-ordered analysis will take place totally outside the carefully constructed congressional scheme embodied in FIFRA. Pesticide producers which sell their products to federal agencies will be subjected to still further layers of federal regulations as each federal agency devises its own testing and research requirements under NEPA. Data submitted to agencies other than EPA will not carry with it the protections, both procedural and substantive, that FIFRA demands and which this Court considered the past Term. See *Ruckelshaus v. Monsanto Company*, ... U.S. ....., 104 S.Ct. 2862 (1984).

Because of Monsanto's concern about the debilitating and contradictory effects of such a duplicative regulatory system, the Company participated in this case as amicus curiae in the Court of Appeals. This Brief addresses the opinion below from the viewpoint of pesticide manufacturers already subject to the comprehensive regulatory scheme of FIFRA.

REASONS FOR GRANTING THE WRIT

1. The tasks assigned to BLM by the Court of Appeals duplicate EPA's responsibilities under FIFRA. FIFRA's comprehensive scheme includes an extensive data review process which EPA undertakes as part of its decision to register a pesticide or to cancel or suspend an existing registration. See, e.g., *Ruckelshaus v. Monsanto Company*, ... U.S. ....., 104 S.Ct. 2862, 2866-70 (1984). All of the products BLM sought to use in its forest spraying program are currently registered by EPA, pursuant to FIFRA, for those very uses. According to the Court of Appeals, BLM cannot rely on EPA's determinations regarding these pesticides. NEPA, the Court ruled, requires each federal agency to conduct an independent scientific evaluation of the potential harmful effects of each pesticide it seeks to use whenever any question is raised about the product's safety. The Court of Appeals did not find defects in EPA's implementation of FIFRA. Instead, it determined as a procedural matter that one agency cannot rely upon the decisions of another in carrying out its NEPA responsibilities. The implications of that determination are far-reaching.

a. Notwithstanding the substantial data required of registrants, and EPA's thorough analysis of that information preceding FIFRA registration, pesticide manufacturers now face entirely new review processes, processes with no data guidelines, standards or consistency in approach. The research and test data now required by EPA to support registration under FIFRA is extensive and costly. EPA's data requirements published in proposed form on November 24, 1982 (47 Fed. Reg. 53192 et seq.) reflect the broad range of complex studies EPA requires of registrants.

These include efficacy technical information, phytotoxicity studies, metabolism and residue studies, environmental chemistry studies, toxicology studies, fish and wildlife studies and manufacturing studies. A single long-term animal feeding study to assess chronic toxicity can itself cost several hundred thousand dollars and can take 4 years. These research and test data, and the trade secrets contained in them, must be furnished to EPA to register a product under FIFRA. *Ruckelshaus v. Monsanto Company, supra,* 104 S.Ct. at 2870-71. Under the Court of Appeals' decision, as subsequently explained in *Merrell v. Block,* No. 83-3908, slip op. 10-11, 14 (9th Cir. Jan. 27, 1984), all federal agencies using pesticides must now analyze this complex data package by undertaking research activities themselves or by requiring registrants which have satisfied EPA to develop even more data.

FIFRA establishes EPA as the "congressionally designated expert on pesticides." *United States v. Goodman,* 486 F.2d 847, 849 (7th Cir. 1973). It is incongruous, and inconsistent with the rule of reason governing NEPA's procedural requirements, for the Court of Appeals to conclude that after enacting FIFRA Congress intended other federal agencies, regardless of their lack of expertise, to stand in EPA's stead. This result threatens pesticide producers with the extraordinary burden of conducting years of additional research and testing whenever a federal agency needs to compile an environmental impact statement ("EIS") before using their product. See *Metropolitan Edison Company v. PANE,* 460 U.S. 766, 776 (1983).[2]

b. Respondent has ignored FIFRA and the decision below encourages it to do so. If any individual

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2. Federal agencies may find it difficult to obtain suppliers for their pesticide needs when these are the consequences.

believes there is a human health risk associated with the use of a pesticide, they may formally request, pursuant to the provisions of FIFRA, that EPA revise or cancel the registration; if the Administrator refuses to do so, they may obtain judicial review. 7 U.S.C. 136n(a). Instead of utilizing the procedures established by Congress, respondent sought to delay use of these products through the creation of a new NEPA-based review process conducted by federal agencies which use the products. Any concerns respondent has about a particular pesticide can and should be addressed to EPA pursuant to FIFRA.

The decision below also deprives registrants such as Monsanto of their rights under FIFRA. Section 6(b) of FIFRA, 7 U.S.C. 136d(b), and EPA's registration regulations in 40 C.F.R. 162.11, ensure that issues regarding the safety of the product are thoroughly considered before a registration is cancelled. Under the NEPA program devised by the Court of Appeals there are no procedural safeguards and thus no assurances that an agency's decision to preclude use of an EPA-registered product was based on a full, accurate understanding of the data. Furthermore, the provisions in FIFRA carefully regulating the use and disclosure of registrants' trade secret data, which Congress developed to protect the interests of registrants within the overall goals of FIFRA, would no longer be applicable.

c. Virtually any pesticide use by a federal agency can be enjoined because no agency other than EPA has conducted the broad-ranging, complex scientific analysis involved in registration of a pesticide. The Court of Appeals' decision has produced precisely that result. Government spraying programs have been enjoined in BLM's Eugene Oregon District, in the Siuslaw National Forest, and in the remainder of the BLM and U.S. Forest Service

areas in Oregon and Washington, as well as portions of Idaho and Northern California. See *Merrell v. Block,* No. 83-3908, slip op. (9th Cir. Jan. 27, 1984); *Save Our Ecosystems v. Watt,* No. 83-3908, slip op. (9th Cir. Jan. 27, 1984); *Northwest Coalition for Alternatives to Pesticides v. Block,* Civ. No. 82-6272, slip op. (D. Or. Jan. 6, 1984), *appeal pending,* No. 84-3821 (9th Cir.). In light of the Court of Appeals' interpretation of NEPA, the spraying of thousands of acres of federal lands will come to a halt, with serious potential adverse impact on timber production, while a redundant scientific review of the pesticides is conducted, possibly taking many years.

d. The principle that NEPA can prevent an agency from utilizing another agency's decision made in accordance with a congressionally-mandated review would not be limited to pesticides. Disagreements over the safety of drugs often accompany Food and Drug Administration ("FDA") implementation of the Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. For example, opponents of use of a particular drug could require that the Veterans Administration or a military installation conduct an independent review of the safety of that drug before allowing it to be used, notwithstanding FDA registration. Products reviewed by other agencies, such as the Consumer Product Safety Commission or the National Highway Traffic Safety Administration, could similarly be subject to duplicate analysis by federal users. Even EPA's establishment of health-based restrictions on emissions from motor vehicles or additives to fuel, pursuant to the Clean Air Act, 42 U.S.C. 7401 et seq., would not be controlling on other government agencies which purchase those products. Such a circumvention of congressional-mandated duties, and a duplication of expertise among agencies, was never contemplated by Congress, or sanc-

tioned by previous courts, as part of the review obligations imposed by NEPA.[3]

2. The problems presented by the Court of Appeals' decision are particularly acute due to the Court's additional misapplication of NEPA in requiring BLM to examine mere possibilities, however remote, of an adverse health effect. The district court found that any "potential harmful effect on human health" must be considered a significant adverse effect requiring further review by the agency, including a "worst case" analysis. *Southern Oregon Citizens Against Toxic Sprays v. Watt*, No. 79-1098FR, slip op. 8 (D. Or. Sept. 9, 1982). The Court of Appeals agreed that the "uncertainty" about the "possibility" of significant adverse effects requires a worst case analysis. *Southern Oregon Citizens Against Toxic Sprays, Inc. v. Clark*, 720 F.2d 1475, 1479 (9th Cir. 1983).[4]

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3. In directing BLM to ignore EPA's determinations under FIFRA, the Court of Appeals misapplied earlier court decisions which caution that an agency may not *abdicate* its responsibilities under NEPA on the basis of decisions made by other agencies. See, e.g., *Citizens Against Toxic Sprays, Inc. v. Bergland*, 428 F.Supp. 908 (D. Or. 1977) and *Calvert Cliffs Coordinating Committee, Inc. v. AEC*, 449 F.2d 1109 (D.C. Cir. 1971). Those cases merely hold that an agency may not let another agency's decision relieve it of the responsibility to apply NEPA's deliberative process and determine its own course of conduct. This does not mean, however, that the agency may not consider - and rely upon - the conclusions of the other agency. The agency subject to NEPA still must make its own determination whether and how to proceed, weighing its proposed action against the foreseeable environmental effects associated with that action. For example, BLM might decide not to use a particular pesticide, even though it is registered by EPA, because of particular site factors or because EPA may have pending possible changes to the registration. EPA's determination regarding the registerability of these pesticides, however, is one of the factors available to BLM in assessing its actions, and BLM must be allowed to rely upon that determination.

4. The regulations of the Council on Environmental Quality ("CEQ") do not require worst case analyses to examine every possible uncertainty about an action. They specifically provide

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Uncertainty about ultimate effects can accompany virtually any federal action; such a criterion for review dramatically increases the number of situations where an EIS can be ordered and greatly expands the research which must be conducted. No amount of empirical data can ever provide 100% assurance that any substance is totally "safe." Thus, by insisting that the only way to avoid independent review or worst case analysis is to prove a negative, the Court of Appeals has ensured there will always be "potential" for harm and "uncertainty" which can be used to compel federal agencies to comply with the new substantive obligations which the Court of Appeals has created.[5]

By requiring federal agencies to undertake such an intensive analysis of speculative risks associated with product safety, the Court of Appeals has burdened federal agencies and has legislated a new layer of regulatory requirements on manufacturers of products such as pesticides and drugs used by those agencies. The research obligation imposed on these agencies by the Court of Ap-

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Footnote continued—

that the worst case analysis is required only when an agency is evaluating significant adverse effects on the human environment in an EIS. 40 C.F.R. 1502.22. "Uncertainty" about the "potential" of human health effects cannot meet the threshold test of "effect" as defined in the CEQ regulations because it cannot be reasonably foreseeable, so the worst case regulation does not come into play. Only when a foreseeable effect exists would a worst case analysis be relevant to ensure data gaps or scientific uncertainty do not leave review of that effect uncompleted. The Court of Appeals has improperly interpreted this limited intent of the worst case regulation to create a procedure for requiring review of speculative events which do not meet the definition of "effect."

5. Even though respondent presented information raising uncertainty about potential health effects of only one (2,4-D) of the 13 herbicides under consideration by BLM, the district court enjoined the spraying of all herbicides pending their review in a worst case analysis.

peals directs them to develop data to *resolve* the uncertainties, not merely to identify the information which has been developed on a particular product and reveal the scientific disagreements so that the decision-maker may consider this information, which is all that NEPA requires. See *Conservation Council of North Carolina v. Froehlke*, 435 F.Supp. 775, 793 (M.D. N.C. 1977).

To avoid such an unbounded expansion of NEPA, it has been consistently held that federal agencies should limit their inquiry to probable effects, avoiding unproductive examinations of remote or highly speculative events. *Warm Springs Dam Task Force v. Gribble*, 621 F.2d 1017, 1026 (9th Cir. 1980). The Council on Environmental Quality ("CEQ") codified this essential limitation by defining the unreasonable adverse "effects" which an agency must examine in an EIS as those consequences which will directly occur or which are "reasonably forseeable." 40 C.F.R. 1508.8. If there is uncertainty about even the possibility of an event, such a possibility cannot be an "effect" which federal agencies must examine. Disregarding this fundamental principle of NEPA led the Court of Appeals into a direct confrontation with FIFRA's congressional scheme, which specifically addresses such issues. In complying with NEPA, federal agencies should build on FIFRA, not be charged with recreating it. "Time and resources are simply too limited . . . to believe that Congress intended to extend NEPA as far as the Court of Appeals has taken it." *Metropolitan Edison Company v. PANE, supra*, 460 U.S. at 776.

CONCLUSION

For the reasons set forth above, this Court should grant the Solicitor General's Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit.

Respectfully submitted,

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